IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MELINDA KILLEN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 11-1508
	)	
STRYKER SPINE, an unincorporated division of Howmedica Osteonics Corporation,	)	Judge Joy Flowers Conti Magistrate Judge Maureen P. Kelly
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

I. RECOMMENDATION

Presently before the Court is Defendant Stryker Spine's ("Stryker")[1] Motion to Dismiss Plaintiff's Complaint. (ECF No. 3) For the reasons that follow, it is respectfully recommended that the Motion to Dismiss be granted in part and denied in part.

II. REPORT

A. FACTUAL AND PROCEDURAL HISTORY

In January 2007, Plaintiff Melinda Killen ("Plaintiff" or "Killen") sustained a spinal injury in an automobile accident. In June 2007, Killen consulted with a neurologist, Dr. Joseph Maroon, concerning cervical pain. Dr. Maroon reviewed the MRI of Killen's spine taken after

[1] Plaintiff initially named Styker Corporation as a defendant in this matter. In response to an argument presented in Defendant's Motion to Dismiss, Plaintiff now agrees that Stryker Corporation is not a proper party to the litigation. On February 10, 2012, this Court entered an Order granting the parties' joint motion to amend the caption and dismissed Stryker Corporation as a defendant in this lawsuit (ECF No. 16).

the accident, determined that she had a herniated disc,[2] and recommended surgery to address the problem.

During this same time period, Stryker was conducting a nationwide clinical trial for its CerviCore Intervertebral Device ("CerviCore"). The device, an artificial disc implant, purportedly would serve as an alternative to traditional cervical surgeries. It was designed to decrease the recovery time following surgery and to allow patients to maintain normal range of motion in their spines following implantation. This was the first time that the CerviCore device would be implanted in humans and the study was conducted under an Investigational Device Exemption ("IDE"), discussed infra, which permitted Stryker to conduct clinical trials to determine the safety and efficacy of the device.

Dr. Maroon's practice group was affiliated with the CerviCore study and recommended Killen as a candidate for the clinical trial. On or about June 25, 2007, Killen agreed to participate in the study and Dr. Maroon implanted the CerviCore device on July 9, 2007.

Although Killen initially experienced relief from neck pain following the surgery, after approximately six weeks, the pain increased. Over the next three months, the pain increased in severity, her radicular[3] symptoms returned, and she developed a sore throat and flu-like symptoms.

In February 2009, Killen noticed a scraping sound when she moved her neck and began to have difficulty swallowing. At an office visit on February 12, 2009, Dr. Maroon noted the

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[2] While plaintiff's Complaint is replete with medical terminology, she does not provide definitions of these terms. For its own edification, the Court sought guidance from internet medical dictionaries and medical websites, but does not attest to the accuracy of the definitions.

[3] Radicular is an adjective meaning relating to the root. STEDMAN'S MEDICAL DICTIONARY (2006).

presence of the sound and prescribed medication to address the pain. At this point, he indicated that Killen's problems were "unlikely related to the artificial disc." Compl. ¶ 25. When Killen's symptoms continued, however, Dr. Maroon suggested that the CerviCore device be removed and spinal fusion surgery be performed. When the device was removed, Dr. Maroon noted that Killen "suffered from cervical spondylosis with radiculopathy[4] and failure of the artificial disc implant . . . [and observed] an 'extraordinary' amount of scaring [sic] at the prior surgical site . . . ." Compl. ¶ 29. The removed device and a sample of plaintiff's tissue and bone were examined by UPMC Presbyterian's Pathology Department which "found evidence of devitalized fibrocartilage and bone fragments . . . and noted the presence of gray and yellow tissue" in Killen's cervical spine, "which is indicative of adverse pathology including but not limited to metal[l]osis."[5] Id. at ¶ 31. In all, Killen underwent four corrective surgeries and, as of the time the Complaint was filed, she continued to experience neck pain.

On July 19, 2011, Killen commenced an action in the Court of Common Pleas of Allegheny County, Pennsylvania, by filing a writ of summons against Stryker Corporation, Stryker Spine, and others. On October 28, 2011, counsel for Stryker Corporation and Stryker Spine received service of the Complaint which named only Stryker Corporation, a Michigan

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[4] Spondylosis is a general term for degeneration of the spine as a person ages. Radiculopathy is the medical term for the pain and other symptoms resulting from a compressed nerve root. People with radiculopathy from cervical spondylosis may experience stiffness and pain in their necks, tingling or numbness in their shoulders or arms, or pain in their shoulders, arms, and chests. http://www.laserspineinstitute.com/back_problems/spondylosis/radiculopathy

[5] "Metallosis" is defined as a "nonsuppurative osteomyelitis that occurs around metal implants as a result of corrosion or hypersensitivity reaction." http://medicaldictionary.thefreedictionary.com/metalosis.

"Nonsuppurative osteomyelitis" is defined as "tuberculosis of the bone." http://medicaldictionary.thefreedictionary.com/nonsuppurative+osteomyelitis.

corporation, and Stryker Spine, an unincorporated division of Howmedica Osteonics Corporation, a New Jersey Corporation. The Complaint asserted claims for negligence (Count I), strict liability (Count II), fraud (Count III), negligent misrepresentation (Count IV), breach of implied warranties (Count V), and breach of express warranties (Count VI).

On November 28, 2011, Stryker Corporation filed a petition for removal from state court based upon diversity jurisdiction.

On December 5, 2011, Defendants filed a Motion to Dismiss the Complaint alleging that all of Killen's claims are preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act ("FDCA"). (ECF No. 3). Defendants additionally contend that dismissal is warranted on the strict liability and breach of implied warranty counts because Pennsylvania law does not recognize these claims in cases involving prescription medical devices. As to the fraud claim, defendants argue that it, and plaintiff's derivative request for punitive damages, must be dismissed because the fraud count is rooted in a failure to warn theory that is not cognizable under Pennsylvania law. Finally, Stryker Corporation argues that it is not a proper party to this litigation, a claim that Killen has conceded. See n.1, *supra*.

B. STANDARD OF REVIEW

The United States Supreme Court opinions in Bell Atlantic Corporation v. Twombly, 550 U.S. 544 (2007) and, more recently, in Ashcroft v. Iqbal, 556 U.S. 662 (2009), have shifted pleading standards from simple notice pleading to a more heightened form of pleading, requiring a plaintiff to plead more than the possibility of relief to survive a motion to dismiss. With the Supreme Court instruction in mind, the United States Court of Appeals for the Third Circuit has outlined a two-part analysis that courts should utilize when deciding a motion to dismiss for

failure to state a claim. First, the factual and legal elements of a claim should be separated. In other words, while courts must accept all of the complaint's well-pleaded facts as true, they may disregard any legal conclusions. Second, courts must then decide whether the facts alleged in the complaint are sufficient to demonstrate that the plaintiff has a "plausible claim for relief." Iqbal, 566 U.S. at 679. That is, a complaint must do more than allege the entitlement to relief; its facts must show such an entitlement. Fowler v. UPMC Shadyside, 578 F.3d 203, 210-211 (3d Cir. 2009).

C. DISCUSSION

1. Overview of Medical Devices Amendments of 1976

The MDA established a federal regulatory regime, creating three classes of medical devices categorized by "the risks they present." Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008); 21 U.S.C. § 360c (enumerating three classes of medical devices and describing their characteristics). Class III devices, such as the CerviCore implant, are intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(I)-(II).

Class III devices receive the most stringent level of federal oversight. Riegel, 552 U.S. at 317; Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 344 (2001) (Class III devices incur FDA's strictest regulation). Before a Class III medical device enters the market, the device's manufacturer must obtain preliminary FDA approval. Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). The FDA's premarket approval process ("PMA") entails a "rigorous" evaluation in which manufacturers submit detailed, voluminous applications to the FDA. Buckman, 531 U.S. at 343. These regulations require a PMA application to include

comprehensive data from which the FDA can make a reasoned determination of the device's safety and efficacy, including human clinical trials, design specifications, manufacturing processes and quality controls, and proposed labeling and advertising. See 21 C.F.R. § 814.20; Riegel, 552 U.S. at 318 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)).

The MDA exempts investigational medical devices, such as the CerviCore disc, from the PMA process. 21 U.S.C. § 360j(g). An Investigational Device Exemption ("IDE") is an experimental regimen that allows for unapproved devices to be utilized in human trials. While manufacturers of these devices need not comply with PMA requirements during the trial period, a detailed application is required to receive an IDE. Id. In sum, the application must describe the device and set forth a plan for studying its use in human subjects during the experimental period. 21 C.F.R. § 812.20. The patient-recipients of a device granted an IDE are informed of the device's investigational status and the risks involved. 21 U.S.C § 360j(g)(3)(D). See also Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090, 1095 (explaining in detail the IDE approval process).

In addition to crafting a federal regulatory structure for medical devices, the MDA contains an express preemption provision. The provision states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In Riegel, the United States Supreme Court instructed that state laws are preempted by the MDA if: (1) "the Federal Government has established requirements" applicable to a particular device; and (2) the plaintiff's claims are based on state requirements related to safety and effectiveness that are "different from, or in addition to" the federal requirements. 552 U.S. at 321–23. The Supreme Court reasoned that a state law mandating a manufacturer's devices "to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme. . . . " Id. at 325. "Included in the meaning of 'state requirements' subject to federal preemption are common law causes of action, such as negligence, strict liability, and breach of implied warranty." Gross v. Stryker, ___ F.Supp. 2d. ___, 2012 WL 876719, at * 11 (W.D. Pa. March 14, 2012)(*quoting* Riegel, 552 U.S. at 324-35); *see also* Williams v. Cyberonics, Inc., 388 F. App'x 169, 171 (3d Cir. 2010) (allegations of strict products liability based on manufacturing defect and breach of warranty, which are "[g]eneralized common law theories of liability," are preempted by the MDA) (quotation omitted).

MDA preemption, however, is not absolute. Riegel allows products liability and implied breach of warranty claims against a manufacturer of a Class III medical device to proceed where the claims are "premised on a violation of FDA regulations" relating to the device. 552 U.S. at 330. To avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards. Williams v. Cyberonics, Inc., 654 F. Supp.2d 301, 306 (E.D. Pa. 2009).

Since the Supreme Court's decision in Riegel, at least one court has held that the MDA preempts state law tort claims regarding medical devices subject to the IDE process. In Burgos v. Satiety, Inc., No. 10-CV-2680 (JG), 2010 WL 4907764 (E.D.N.Y. Nov. 30, 2010), the court noted that claims of negligence, strict liability and breach of warranty were preempted

"[b]ecause IDE devices are subject to a level of FDA oversight and control that is, for the purpose of a preemption analysis, identical to that governing PMA devices." Id. at *2. Killen does not dispute that the body of MDA preemption law is applicable herein.

2. Overview of Motion to Dismiss

Stryker seeks the dismissal of Killen's entire Complaint for failure to state a claim upon which relief may be granted. First, Stryker argues that Killen's claims for strict liability, negligence and breach of implied warranty, as well as breach of express warranty, fraud and negligent misrepresentation, are preempted by the MDA. (ECF No. 4 at 8-15). Second, Stryker contends that the strict liability, breach of implied warranty and fraud claims are also preempted under Pennsylvania law. (ECF No. 4 at 16-21). Third, Stryker argues that Killen's derivative claim for punitive damages should be dismissed. (ECF No. 4 at 21).

In her Response in Opposition to Motion to Dismiss for Failure to State a Claim (ECF No. 11), Killen proposes that her negligence claim does not succumb to MDA preemption because her claims, while not citing individual device specific federal regulations, closely track and parallel the federal regulations for medical devices approved for an IDE. While Stryker describes Killen's argument in this regard as a concession that the MDA preempts her strict liability, negligence and breach of warranty claims, in her sur-reply brief, Killen rejects this characterization of her position, insisting that the exception for parallel claims applies as well to her non-negligence causes of action.

a. Negligence (Count I)

While Stryker contends that MDA preemption jettisons plaintiff's negligence claim, Killen counters that her Complaint cites cognizable parallel claims of alleged violations of

federal regulations promulgated pursuant to the MDA, thereby exempting her claim from preemption.

In Riegel, the United States Supreme Court noted an exception to MDA express preemption under § 360k(a) for parallel claims. The Court stated that the MDA does not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," because, in such instances, the state law duties would "parallel" rather than "add to" the relevant federal requirements. 552 U.S. at 330 (*citing* Medtronic, 518 U.S. at 513).

Recently, in Gross v. Stryker, Judge Nora Barry Fischer of this Court conducted a thorough review of parallel claim jurisprudence. Judge Fischer first observed that allegation of a proper parallel claim requires the complainant to "set forth facts showing action or inaction in [defendants'] efforts to take part in the PMA process or implement its results." Gross, 2012 WL 876719 at *18 (internal citations and quotations omitted). See also Williams, 654 F. Supp.2d. at 306 (to avoid federal preemption, plaintiff must make some showing that medical device was not manufactured in accordance with FDA standards). Judge Fischer also recognized that, in addition to the pleading requirements necessary to overcome Section 360k express preemption, private plaintiffs face the further hurdle of circumventing implied MDA preemption. Under 21 U.S.C. § 337(a), all proceedings for the enforcement or to restrain violations of the FDCA "shall be by and in the name of the United States." In construing § 337(a), the United States Supreme Court observed that "the FDCA leaves no doubt that it is the Federal Government rather than private litigants [which is] authorized to file suit for noncompliance with the medical device provisions" in the FDCA. Buckman, 531 U.S. at 349 n.4. "As a result, 'Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express

or implied preemption.'" Gross, 2012 WL 876719 at *19 (quoting Riley v. Cordis Corporation 625 F. Supp.2d 769, 777 (D. Minn. 2009)).

While the precepts of express preemption under Section 306k and implied preemption under section 337(a) would appear to basically foreclose litigation of parallel claims, two types of claims have been identified which can potentially survive preemption: 1) "'an adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications;'" and, 2) "a claim brought under a state statute 'providing a remedy for a violation of the FDCA.'" Gross, id. (*quoting* In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp.2d 1147, 1161, n.17 (D. Minn. 2009).

Since there is no Pennsylvania statute permitting a private cause of action for FDCA violations, Killen's parallel claims can proceed only if she has sufficiently pled that the CerviCore implant was not manufactured in conformity with its IDE. While Killen initially asserts that she is disadvantaged at this stage of the litigation because she does not have access to the confidential IDE agreement between Stryker and the FDA, she nonetheless argues that her Complaint includes three parallel claims which are not preempted by the MDA.

Plaintiff first avers that Stryker violated 21 C.F.R § 820.100(a)(6) and (7) which outlines medical device manufacturers' duties regarding corrective and preventive action. This section provides that:

> (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:
>
> * * *
>
> (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

> (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

21 CFR § 820.100(a)(6)(7).

In her response to Defendant's Motion to Dismiss, Killen urges that her allegation that Stryker was negligent in "failing to keep proper records of the design, manufacturing and testing of the CerviCore device" and in "failing to identify, disclose and correct, in a timely fashion, that the CerviCore implant had design and/or manufacturing flaws that increased the risk of serious injury to patients undergoing cervical disc replacements" parallels this regulation. Compl., ¶¶ 40(l), 40(n).

Killen next claims that Stryker violated 21 C.F.R. § 820.70(e) and (h), requiring manufacturers to "establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality," and to "establish and maintain procedures for the use and removal" of manufacturing material (such as lubricants or abrasives, or cleaning and disinfectant agents) "to ensure that it is removed or limited to an amount that does not adversely affect the device's quality." As to this regulation, Killen's Complaint alleges that Stryker failed to properly design the device because it "compromis[ed] the integrity of the CerviCore implant components through the use of titanium coating techniques . . . ." Compl. ¶ 40(a).

Killen's third asserted parallel claim is that Stryker's failure to "provide proper warnings, and instructions to the medical community and the community of prospective patients relative to the limitations and defects in the CerviCore implant, including, but not limited to . . . the use of nickel in the device, and the risks of metallosis," (Compl. ¶ 40(d)), violated 21 C.F.R. § 812.5(a), which requires medical device manufacturers to describe "all relevant contradictions, hazards,

adverse effects, interfering substances or devices, warnings and precautions."

Stryker responds that Killen's assertion of parallel claims falls short for two reasons: first, two of the federal regulations substantiating her parallel claims, namely §§ 820.100 and 820.70, are Current Good Manufacturing Practices ("CGMPs") provisions that cannot serve as a basis for parallel claims related to an IDE device; and, second, even if the CGMPs applied to the CerviCore implant, Killen's broad non-specific allegations of violations of federal regulations are insufficient to avoid dismissal under Twombly/Iqbal pleading requirements.

On the related questions of whether CGMPs provisions can provide the foundation for a parallel claim and the requisite pleading specificity mandated by Twombly/Iqbal, Gross, again, is instructive.

Although recognizing that the United States Court of Appeals for the Third Circuit has not spoken on the required specificity for pleading parallel claims, Judge Fischer determined that "broad references to federal regulations" cannot establish the essential duty element of a state law negligence claim paralleling a violation of federal law. Gross, 2012 WL 876719, at *20. Rather, to state a plausible claim to avoid MDA preemption, a plaintiff must plead sufficient facts to state a facially plausible claim that relies on "'more than labels and conclusions, and a formulaic recitation of the elements of a cause of action.'" Id. (quoting Twombly, 550 U.S. at 555).

Gross reviews decisions from other courts holding that alleged violations of CGMP's are not sufficient to evade MDA preemption since they "do not address the specific aspects of a particular medical devices design, production and marketing requirements." Id. at *21 (citing Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009). See also In re Medtronic, 592 F. Supp.2d at 1158 (CGMP's, standing alone, cannot serve as basis for manufacturing defect

claims); Horowitz v. Stryker Corporation, 613 F. Supp.2d 271, 279 (E.D.N.Y. 2009) (to extent that plaintiff cannot establish link between noncompliance with a particular condition of PMA and her cause of action, a parallel claim will fail).

Gross acknowledges that the area of law concerning parallel claim exemption is a developing one and examines recent decisions where other courts have concluded that CMGPs may serve as a basis for a parallel claim. See e.g., Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 436, 440–41 (6th Cir. 2010)(21 C.F.R. § 820.70(h) not so vague as to be incapable of enforcement); Gelber v. Stryker Corporation 788 F. Supp.2d 145, 159 (S.D.N.Y. 2011) (plaintiff's claim that manufacturer of artificial hip prosthesis failed to adhere to CGMP's stated New York common law negligence claim); Bass v. Stryker Corporation, 669 F.3d 501 (5th Cir. 2012) (reliance on CGMPs not critical to successfully pleading parallel claim; essential elements to parallel claim are existence of a manufacturing defect caused by violation of federal regulations *and* allegations connecting defect in the manufacture of the specific device to plaintiff's specific injury); Bausch v. Stryker Corporation, 630 F.3d 546, 555–56 (7th Cir. 2010) (declining to differentiate between general requirements and device-specific requirements and opining that violations of both could feasibly survive preemption). Gross, 2012 WL 876719 at *21.

The Gross court declined to apply the line of cases permitting parallel claims to proceed in its case for a variety of reasons. First, the pleadings failed to meet the specificity requirements of Twombly/Iqbal; second, the regulation relied upon was distinguishable from the general regulations that the Gross plaintiff claimed were violated; and, third, under Riegel, only violations of device specific claims can serve as the basis of a parallel claim. The Gross court concluded that the plaintiff's complaint failed to outline the specific regulations and describe

how Stryker violated those regulations and, thus, did not state a parallel claim for negligence that could survive preemption under to meet the Twombly/Iqbal pleading standards. Gross, 2012 WL 876719 at *22, 23.

While this Court agrees in substance with the legal rationale expressed in Gross, this matter is distinguishable because Killen has, at this stage of the proceedings, sufficiently pled parallel claims. Moreover, the Court does not accept the blanket position that CGMPs can never serve as the basis for a parallel claim. Instead, the issue is whether Killen has advanced an adequately pleaded claim that the CerviCore implant was not manufactured in accordance with its IDE specifications and in violation of FDA regulations. To review, Killen's Complaint avers that Stryker: (1) was negligent in its record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant and argues that this activity violated the manufacturer's duty to establish and maintain procedures for implementing corrective and preventative action under 21 § 800.100(a)(6)(7); (2) was negligent in compromising the integrity of the CerviCore implant by utilizing titanium coating techniques, in violation of 21 C.F.R. § 820.70(e),(h)[6]; and, (3) failed to provide proper warnings concerning defects in the device, including the use of nickel and the risks of metallosis, in violation of a manufacturer's duty outlined in 21 C.F.R. § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions." In her sur-reply brief, Killen also refers to the allegation in the Complaint that Stryker was negligent in performing metal allergy testing prior to accepting patients into the clinical trial, but admits that, without discovery, she cannot identify specific regulations requiring such testing.

These descriptions of purported regulatory violations go beyond the rote conclusory

[6] The Court notes that this same regulation was construed in Howard, 382 F.3d at 440–41, as a sufficient basis on which to base a parallel claim.

pleadings that the Gross court found insufficient to sustain parallel claim allegations. Additionally, while the Court acknowledges that under Riegel, Killen must eventually allege a device-specific claim, it disagrees with those cases holding that a plaintiff is subject to this standard at the motion to dismiss stage. It is disingenuous to identify the parallel claim exception to MDA exemption as articulated in Riegel, but foreclose plaintiffs any opportunity to prove the exception. As recognized in Burgos v. Satiety, 2011 WL 1327684 (E.D.N.Y. 2011):

> [P]laintiffs alleging state-law parallel claims based on a violation of a manufacturer's agreement with the FDA often suffer from a unique disadvantage: the agreements (including IDEs) that would provide the necessary factual specificity are confidential, and available only to the defendants and the FDA. [A]plaintiff's pleading burden should be commensurate with the amount of information available to them. Other courts have similarly observed that it would be an injustice to penalize a plaintiff for alleging, through no fault of her own, what turned out to be insufficient facts about the manufacturing process of a device that caused injury. See Hofts v. Howmedica Osteonics Corp., 597 F. Supp.2d 830 (S.D. Ind. 2009); see also Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010).

Id. at *4 (citing In re Medtronic, Inc., Spring Fidelis Leads Products Liability Litigation, 623 F.3d 1200 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part and noting injustice arising from court's decision to rigidly adhere to Twombly, rather than pragmatically evaluate the complaint in context of plaintiff's informational limitations). Thus, in this unique set of circumstances, where Killen has advanced facts that suggest the existence parallel claims, but does not have access to the confidential information to specifically plead the alleged violation of FDA regulations, fairness compels that some leniency be afforded plaintiff from the stringent Twombly/Iqbal pleading standards to allow this claim to proceed.

It is, therefore, recommended that the Motion to Dismiss the negligence claim (Count I) be denied.

b. Strict Liability (Count II)

Pennsylvania law recognizes three different types of defects that can give rise to a strict-liability claim: design defect, manufacturing defect, and a failure to warn. Phillips v. A–Best Products Company, 542 Pa. 124, 665 A.2d 1167, 1170 (Pa. 1995). Killen advances all three theories of strict liability. Stryker argues that comment k of Section 402A of the RESTATEMENT (SECOND) OF TORTS mandates dismissal of Killen's strict liability claims.

In Hahn v. Richter, 543 Pa. 558, 673 A.2d 888 (1996), the Pennsylvania Supreme Court decided that strict liability claims based upon a failure to warn theory cannot be brought against prescription drug manufacturers. The Supreme Court relied upon and adopted comment k of §402, titled Unavoidably Safe Products and reading:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken

> to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

543 Pa. at 561, n.2.

Although the Pennsylvania Supreme Court has not addressed whether Hahn applies to medical device manufacturers, the Pennsylvania Superior Court has applied comment k to medical devices, finding "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. 2006). Similarly, a number of United States District Courts applying Pennsylvania law have extended Hahn's holding to bar strict liability claims against medical device manufacturers. See Kee v. Zimmer, Inc., ___ F. Supp.2d. ____, 2012 WL 1758618, at *2 (E.D. Pa. May 17, 2012) (as matter of Pennsylvania law, there is no strict liability for harm caused by medical devices); Horsmon v. Zimmer Holdings, Inc., Civil Action No. 11–1050, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011) (predicting that Pennsylvania Supreme Court would apply comment k to prescription medical devices); Soufflas v. Zimmer, Inc., 474 F. Supp.2d 737, 750 (E.D. Pa. 2007) (granting summary judgment for manufacturer on strict liability claim based upon comment k); Davenport v. Medtronic, Inc., 302 F. Supp.2d 419, 442 (E.D. Pa. 2004) (comment k precludes application of section 402A to medical devices); Parkinson v. Guidant Corporation, 315 F. Supp.2d 741, 747 (W.D. Pa. 2004) (prohibition against strict liability claims based on unavoidably unsafe products extended to prescription medical devices).

In the case at issue, Stryker asserts that comment k precludes all of Killen's strict liability claims. In response, Killen argues that even if Hahn applies to medical device manufacturers, there is authority for the Court to recognize the caveat in comment k that drug manufacturers are shielded from strict liability only if their products are "properly prepared, and accompanied by proper directions and warnings." Comment k to §402A.

While other jurisdictions have recognized the comment k caveat relied upon by Killen, some courts interpreting Pennsylvania law do not. See Horsman, 2011 WL 5509420, at *2 (observing that Pennsylvania law does not recognize comment k's caveat and dismissing claim for strict liability); See also Parkinson, 315 F. Supp. 2d at 747 (under Pennsylvania law, § 402A strict liability is precluded entirely for prescription medical devices; comment k caveats are "evaluated under negligence, not strict liability, principles").

Contrary authority also exists. Recently, in Doughtery v. C.R. Bard, Inc., C. A. No. 11-6048, 2012 WL 2940727 (E.D. Pa. July 18, 2012), the United States District Court for the Eastern District of Pennsylvania thoughtfully analyzed the reach of Hahn. The court determined that while Hahn instructs that strict liability does not apply to failure to warn claims, and that the Pennsylvania Superior Court decision in Lance v. Wyeth, 4 A.3d 160, 165 (Pa. Super. 2010), *appeal granted,* 609 Pa. 269, 15 A.3d 429 (2011), disallows design defect strict liability claims, comment k's exemption from strict liability does not extend to manufacturing defects. Doughtery, 2012 WL 2940727, at *6.

After reviewing the decisions on this issue, this Court aligns itself with the reasoning expressed in Doughtery. First, those cases which read Hahn broadly to preclude all strict liability claims do not separately analyze the three theories of strict liability; rather they conclude, without discussion, that Hahn bars the full range of strict liability claims. Such a conclusion is not warranted by Hahn which only evaluated whether strict liability was a proper basis for recovery in a failure to warn case. Second, Killen's claims that the CerviCore device was defectively manufactured, i.e., "the device components were not properly heat treated" and were not made "in a facility . . . that was capable of maintaining the high tolerances and surface preparation needed to reduce wear on metal implants," and "the device had been altered from the

condition in which it was approved for an IDE (Compl. ¶48 (a) and (i)), sufficiently allege, at this stage of the proceedings, that the medical device was not "properly prepared," a prerequisite to comment k applicability when a manufacturing defect is alleged.[7]

Because neither Hahn nor other Pennsylvania law precludes Killen's manufacturing defect strict liability claims, it is recommended that the Motion to Dismiss Killen's manufacturing defect claim be denied. Conversely, Pennsylvania law does not recognize Killen's design defect and failure to warn claims, and it is recommended that that Motion to Dismiss these claims be granted.

c. Breach of Implied Warranty (Count V)

Stryker also asserts that Killen's breach of implied warranty claim (Count V) is preempted under Pennsylvania law. Killen responds as she did to the strict liability issue – that the caveats to comment k of §402A prevent manufacturers from avoiding liability for breach of implied warranty when their products are not of merchantable quality nor fit for their intended use.

i. Implied Warranty of Merchantability

To establish a claim for breach of the implied warranty of merchantability, a plaintiff must establish that the "seller was a 'merchant' and that the goods were not 'merchantable' at the time of the sale." M. Leff Radio Parts, Inc. v. Mattel, Inc., 706 F. Supp. 387, 395 (W.D. Pa. 1988) (quotation omitted); See also 13 Pa.C.S. § 2314(b)(3) (merchantable goods must be fit for ordinary purposes for which such goods are used).

In Makripodis v. Merrell-Dow Pharmaceuticals, Inc., 523 A.2d 374, 377 (Pa. Super.

[7] Further, because Killen has alleged that the CerviCore implant was not manufactured in accordance with its IDE specifications and in violation of FDA regulations, her manufacturing defect strict liability claim, to the extent it is based on manufacturing defects that violate the FDA's CGMP's or are inconsistent with Stryker's manufacturing processes or procedures that were approved by the FDA, is not preempted by the MDA.

1987), the Pennsylvania Superior Court held that "the very nature of prescription drugs" precludes claims based upon the implied warranty of merchantability. Federal district courts in Pennsylvania courts read Makripodis to preclude claims against medical device manufacturers for breach of implied warranties. See Horsmon, 2011 WL 5509420 , at *3 (agreeing with other courts that Makripodis applies to medical devices and precludes cause of action for implied warranty of merchantability claim); Soufflas, 474 F. Supp.2d at 752 (unavoidably unsafe nature of medical devices excludes implied warranty of merchantability claim); Parkinson, 315 F. Supp.2d at 752–53 (Pennsylvania law prohibits claims for breach of implied warranties of merchantability and fitness for particular purpose for medical devices). Additionally, the court in Horsmon observed that Makripodis determined that the "nature of prescription drugs, not comment k, precludes implied warranty claims." 2011 WL 5509420 at *3.

Recently, in Dougherty, the court agreed "with these courts insofar as they held that comment k precludes implied warranty claims against manufacturers of prescription drugs and devices to the same extent that it precludes strict liability claims against manufacturers." 2012 WL 2940727 at *7. Consistent with the finding in Dougherty, to the extent that Killen's implied warranty claim is based on a failure to warn or design defect, it is not cognizable under Pennsylvania law and must be dismissed.

However, because this Court has concluded that Pennsylvania law does not preclude a parallel strict liability claim for a manufacturing defect (to the extent it does not impose requirements that are "different from, or in addition to" the requirements imposed by federal law), it is recommended that at this early stage of the proceedings, the Motion to Dismiss be denied to the extent Plaintiff's breach of implied warranty may be based upon a manufacturing defect which also occurred in the violation of applicable device specific FDA requirements. See,

Bass v. Stryker Corp., 669 F.3d 501 (5th Cir. 2012); but see Gross v. Stryker, ___ F. Supp.2d ___, 2012 WL 876719 *17 (W.D. Pa. 2012) (where Complaint does not indicate that Plaintiff's claim of breach of implied warranty alleges violations of federal regulations, the Court cannot permit claim to proceed where the Court would thereby impose different or additional requirements on a device related to safety and effectiveness). Because Plaintiff has alleged facts supporting a manufacturing defect which also occurred in violation of applicable federal regulations, it is recommended that she be permitted to amend her Complaint to allege additional detailed facts in support of this claim as may be revealed through the course of discovery.

ii. Implied Warranty of Fitness for Particular Purpose

In Doughtery, the court distinguished the underlying basis of liability for a claim alleging the breach of an implied warranty of fitness for a particular purpose, finding it "inconsistent with the policy underlying comment k to find an *implied* promise by the manufacturer that the product is suitable for a particular purpose and to subject the manufacturer to strict liability for a personal injury resulting from a breach of that implied promise." 2012 WL 2940727 at *7

> While an implied warranty of merchantability "is based on the seller's implicit representation that the product will safely and effectively perform the normal functions for which that type of product is ordinarily bought and sold," an implied warranty of fitness for a particular purpose "is an implied promise by the seller that the product sold will meet the buyer's particular needs." 1 Madden & Owen on Products Liability § 4:8, at 154. It is "based upon a special reliance by the buyer on the seller to provide goods that will perform a specific use envisaged and communicated by the buyer." Gall, 555 A.2d at 790. *A claim for breach of the implied warranty of fitness for a particular purpose does not require that a product be defective; rather, this warranty "may be breached when a product properly made and merchantable is simply the wrong one for the buyer's particular use*." 1 Madden Owen on Products Liability § 4:8, at 162; see also id. (explaining that "the concepts of merchantability and defectiveness are unrelated to claims for breach of the implied warranty of fitness for a particular purpose").

Id. (*italics supplied).* Because liability for breach of an implied warranty of fitness for a particular purpose is not measured by the proper manufacture of a medical device, but by the

appropriateness of the device for a particular buyer, liability pursuant to 13 Pa.C.S.A. § 2315 imposes different or additional requirements beyond applicable federal regulations and so does not give rise to a cognizable parallel claim. It is therefore recommended that the Motion to Dismiss be granted as to Killen's claim for breach of implied warranty of fitness for a particular purpose.

d. Breach of Express Warranty (Count VI)

In Count VI of the Complaint, Killen alleges that Stryker expressly warranted in its "written literature, representations and documentation" that CerviCore was "safe, effective, fit and proper for the use for which [it] was intended." Compl. ¶ 81.

In support of its Motion to Dismiss, Stryker argues that express warranty claims in the context of IDE devices are preempted by the MDA. However, Stryker does not cite to any decisions from the Third Circuit in support of its argument.

Federal courts within Pennsylvania have split on the issue of whether breach of express warranty claims are cognizable in the medical device context. Some courts have implicitly recognized express warranty claims as viable causes of action against manufacturers of prescription drugs and devices. See, e.g., Kee v. Zimmer, Inc., No. 11-7789, 2012 WL 1758618, at *3 (E.D. Pa. May 17, 2012); Horsman, 2011 WL 5509420, at *3-4; Kester v. Zimmer Holdings, Inc., No. 2:10–cv–00523, 2010 WL 2696467, at *10–11 (W.D. Pa. June 16, 2010). However, other courts have held that Pennsylvania law precludes such express warranty claims. See, e.g., Aaron v. Wyeth, No. 07–0927, 2010 WL 653984, at *11 (W.D. Pa. Feb.19, 2010); Kline v. Pfizer, Inc., No. 08–3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008); Colacicco v. Apotex, Inc., 432 F. Supp.2d 514 (E.D. Pa.2006), *aff'd on other grounds*, 521 F.3d 253 (3d Cir. 2008), vacated ___U.S. ___, 129 S. Ct. 1578, 173 L.Ed.2d 672 (2009). It is the finding of

this Court that Pennsylvania law does not preclude express-warranty claims against manufacturers of prescription drugs and devices, such as Stryker.

Under Pennsylvania law, an express warranty "arises out of the representations or promises of the seller," 13 Pa. Cons. Stat. § 2313, and must be "directed at consumers in order to induce purchases of the product," Yurcic v. Purdue Pharma, L.P., 343 F. Supp.2d 386, 394–95 (M.D. Pa. 2004) (internal citations omitted). Additionally, express warranties are created by a seller, "inter alia, through any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." Parkinson v. Guidant Corp., 315 F. Supp.2d at 751 (*quoting* 13 Pa. Cons. Stat. § 2313). A plaintiff meets the basis of the bargain requirement by "proving that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise." Id. (quoting Cipollone v. Liggett Group, Inc., 893 F.2d 541, 567 (3d Cir. 1990), *rev'd on other grounds*, 505 U.S. 503 (1992). See also Gross, 2012 WL 876719, at *27 (absent demonstration that promise or affirmative statement was made, how or by whom promise was made, or what was in fact promised, claim for breach of express warranty is not sufficiently pled.").

In the medical device context, a plaintiff typically states a cause of action for breach of express warranty by alleging that a defendant manufacturer has deviated from the FDA approved labeling and instructions for use through voluntary statements to third parties in the course of its marketing efforts. See, e.g., Cornett v. Johnson & Johnson, 2012 WL 3210943, ___ A.3d ___ (N.J. August 9, 2012), *citing* Horn v. Thoratec Corp., 376 F.3d 163, 170 (3d Cir. 2004), Horowitz v. Stryker, 613 F. Supp.2d 271, 285 (E.D.N.Y. 2009) ("[i]n order to avoid preemption, the plaintiff's breach of express warranty claim must 'identify specific representations of the

manufacturer which exceed the scope of the FDA approved statements, thereby establishing a contractual obligation voluntarily entered into by the manufacturer'").

At this point, Killen's Complaint does not sufficiently allege how or by whom a promise was made or what exactly was promised. Without factual support, description of a specific promise that became the basis of the bargain, or a showing that the promise was directed at her, Killen's express warranty claim cannot escape dismissal. See Kester v. Zimmer Holdings, Inc., No. 2:10–cv–00523, 2010 WL 2696467, at *10–11 (W.D. Pa. June 16, 2010) (dismissing a breach of express warranty claim against a pain pump manufacturer for failing, under Twombly, to state a claim under Pennsylvania law).

It is, therefore, recommended that the Motion to Dismiss be denied as to Count VI of the Complaint and that Killen be permitted to amend her Complaint to allege additional detailed facts, if any, in support of her breach of express warranty claim.

e. Fraud and Negligent Misrepresentation (Counts III and IV)

Count III (fraud) of Killen's Complaint alleges that Stryker intentionally misrepresented that the CerviCore implant was safe for human clinical trials and that it had performed all the necessary testing, research, and inspections that are prerequisite to human trials. She also claims that the device used in the clinical trials had been altered prior to its implantation and that Stryker falsely assured her that she would receive adequate medical care in exchange for her participation in the study.

In Count IV (negligent misrepresentation), Killen alleges that Stryker negligently misrepresented and communicated to her and/or her physician the facts underlying her fraud claim in order to obtain participants for the CerviCore clinical trial and that it failed to exercise reasonable care in communicating accurate information about the safety of the device.

Styrker responds that the MDA expressly and impliedly preempts both claims, and additionally argues that the fraud claim is prohibited under Pennsylvania law.

i. MDA preemption

Stryker contends that Killen's claims of fraud and misrepresentation essentially take issue with the labeling of and factual distortions regarding the implant and that such challenges are expressly preempted by the MDA. As recognized by Riegel, the PMA process (and, inferentially, the IDE process) "involves a determination that the FDA-approved label for the subject medical device is neither 'false nor misleading,' and that state common law requirements for additional warnings are preempted." Timberlake v. Synthes Spine, Inc., Civil Action No. V-08-04, 2011 WL 711075, at *7 (S.D. Tex. February 18, 2011) (quoting Riegel, 552 U.S. at 318, 329). Stryker urges that FDA regulations police the entirety of product labeling and representations that can, or cannot, be made in connection with investigational devices. See, e.g., 21 C.F.R. §812.5(a) (label on investigational device must bear warning that it for investigational purposes and describe "contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions"); 21 C.F.R. § 812.25(f) (manufacturer must submit label to FDA for review as part of application process); 21 C.F.R. § 812.25(g) (manufacturer must submit consent form to be signed by participant to FDA for review as part of application process). Stryker particularly references 21 C.F.R. § 812.7(d) prohibiting "[r]epresent[ations] that an investigational device is safe and effective for the purposes for which it is being investigated," to demonstrate that Killen's fraud and misrepresentation claims are preempted because, at their heart, these claims propose that manufacturers must provide warnings beyond those on the device's label and would impose requirements different from or in addition to those approved by the FDA.

Killen's replies that these claims escape MDA preemption because they are based upon representations outside the purview of the FDA's oversight of investigational devices and concern statements made directly to her and her physicians about the device's safety.

The Court agrees with Stryker that Killen's claim of fraud and negligent misrepresentation based upon Stryker's written declarations that it had performed all of the necessary testing, research, and inspections that are prerequisite to human trials are expressly preempted by the MDA. To prevail on these allegations, Killen would have to prove that Stryker's statements about its compliance with FDA human trial regulations were false and misleading and the labeling and literature failed to provide sufficient warning to prospective patients. The MDA, enacted to prevent states from imposing additional or different medical device requirements, preempts a lawsuit challenging the sufficiency of a warning in the product literature. See Riegel, 552 U.S. at 323; 21 U.S.C. § 360k(a). Further, Killen's theory challenges the FDA's oversight and enforcement of regulations governing the labeling of investigational devices and is therefore impliedly preempted by the FDCA. Buckman, 531 U.S. at 349, n.4.

A similar conclusion is not warranted, however, on Killen's fraud and misrepresentation counts based on her allegation that Stryker falsely represented that she would receive appropriate medical care. On this claim, the Court agrees that Stryker's purported misstatements were made directly to plaintiff or her physicians and concern matters beyond the scope of the FDA's regulation of investigational devices. For the same reason, i.e., that the misrepresentations concerning medical care are not within FDA purview, Stryker's argument that this claim is impliedly preempted by the observation in Buckman, 531 U.S. at 349, n.4, that the FDCA does not provides for a private cause of action against the FDA, is unavailing.

ii. Pennsylvania Law

It remains to be decided if Killen's remaining claim of fraud tied to Stryker's statements concerning her medical care is preempted by Pennsylvania law.

In Kester v. Zimmer Holdings, No. 2:10-cv-00523, 2010 WL 4103553 (W.D. Pa. Oct, 18, 2010), plaintiff sued a prescription drug manufacturer claiming that it fraudulently concealed information about the product's risks and dangers for the patient and the medical community. The district court determined that the plaintiff's claims were rooted in a failure to warn theory and, as such, were not cognizable under Pennsylvania jurisprudence declaring negligence as the only theory permitting recovery on a drug manufacturer's failure to warn. Id. at *4.

While Kester's holding suggests that Pennsylvania law would preempt Killen's fraud claims concerning Styker's representations concerning the testing, research, and inspection of the CerviCore device and its supposed alteration, it cannot be read to encompass Killen's medical care allegation. This particular contention describes actions beyond a failure to warn and may proceed under Pennsylvania law.

It is, therefore, recommended that the Motion to Dismiss be granted as to the allegations of fraud (Count III) and negligent misrepresentation (Count IV) concerning the testing, research, and inspection of the CerviCore implant, but denied as to the allegations of fraud and negligent misrepresentation concerning Stryker's alleged representations concerning Killen's medical care.

f. Punitive Damages

Killen's request for punitive damages claim is derived from her fraud claim. As this cause of action remains partially viable, it is respectfully recommended that the Motion to Dismiss this derivative claim be denied at this stage of the litigation.

III. CONCLUSION

For the reasons stated above, it is respectfully recommended that Stryker's Motion to Dismiss be granted in part and denied in part, as follows:

a. COUNT I – NEGLIGENCE. It is recommended that the Motion to Dismiss be denied as to Plaintiff's cause of action alleging negligence;

b. COUNT II – STRICT LIABILITY. It is recommended that the Motion to Dismiss be granted as to Plaintiff's strict liability design defect and failure to warn claims but denied as to Plaintiff's strict liability manufacturing defect claim;

c. COUNT III – FRAUD. It is recommended that the Motion to Dismiss be granted as to Plaintiff's fraud claims arising out of its product literature and labeling, but denied as to claims arising out of Defendants' alleged intentional misrepresentations concerning Killen's medical care;

d. COUNT IV – NEGLIGENT MISREPRESENTATION. It is recommended that the Motion to Dismiss be granted as to Plaintiff's claim alleging negligent misrepresentations in product literature and labeling regarding the testing, research, and inspection of the CerviCore implant, but denied as to Plaintiff's claim arising out of Defendants' alleged negligent misrepresentations concerning Killen's medical care;

e. COUNT V – BREACH OF IMPLIED WARRANTIES. It is recommended that the Motion to Dismiss be granted as to Plaintiff's claim for breach of implied warranty of fitness for a particular purpose, but denied as to Plaintiff's claim for breach of implied warranty of merchantability;

f. COUNT VI – BREACH OF EXPRESS WARRANTIES. It is recommended that the Motion to Dismiss be denied as to Plaintiff's breach of express warranties claim;

g. COUNT VII – PUNTIVE DAMAGES. It is recommended that the Motion to Dismiss be denied as to Plaintiff's claim for punitive damages.

In accordance with the Magistrate Judges Act, 28 U.S.C. § 636(b)(1), and Local Rule 72.D.2, the parties are permitted to file written objections in accordance with the schedule established in the docket entry reflecting the filing of this Report and Recommendation. Failure to timely file objections will waive the right to appeal. Brightwell v. Lehman, 637 F.3d 187, 193

n. 7 (3d Cir. 2011). Any party opposing objections may file their response to the objections within fourteen (14) days thereafter in accordance with Local Civil Rule 72.D.2

Dated: August 21, 2012

Respectfully submitted,

/s/Maureen P. Kelly
MAUREEN P. KELLY
United States Magistrate Judge

cc: The Honorable Joy Flowers Conti
United States District Judge

All counsel of record by Notice of Electronic Filing